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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,843	03/05/2002	Naoki Usui	220215US0CONT	1934
22850	7590	02/20/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			LEVY, NEIL S	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 02/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/087,843	Applicant(s) USUI ET AL.	
	Examiner Neil Levy	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/30/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7, 9, 13, 15, 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 6, 9, 13, 15 are rejected.
- 7) ☒ Claim(s) 7, 10, 13, 16 are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 6, 9, 12, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of record is maintained; in essence, all that is (claim 5) required is feeding a neutral amine HCl salt compound that drops urine pH to 6.5-5.5. The prior art has that, and few indications are shown in the specification are shown in the specification; fewer still claimed, of when the feeding would be required. To compound the problem, consists essentially refers to the unspecified amino compound, as examiner reads the claim (5). If extension to changing pH is intended, it is not clearly evident to be within consisting essentially. Further it is not at all clear what is intended to be included and excluded by consisting essentially, since there is no identification of what constitutes, or how one in the art determines a needy ruminant, and the composition is unlimited except as a feed with the amino compound. The prior office action, while enabling claim 8, also acknowledged the time at which the ration was fed – prior to parturition. This is no longer the case, so applicants' arguments are not persuasive.

Claims 5-6, 9, 12, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rode et al. EP 0610957 or Sato et al 5,906842 in view of Itagaki et al 033698 and further in view of Davidson et al '95.

The rejection of record is maintained, Rode (above) feeds the instant neutral amino acid forms, Pre-partum, to Dairy cows and increases milk production, with out incidence of milk fever. However, all of the forms are not reported, nor was urine pH measured. Sato likewise feeds the instant amino acids, but not specifically identified as neutral (summary). The amounts feed are palatable, and effective (col. 3, lines 40-62, col. 4, lines 12-18). Milk production increase is seen; milk fever is not (col. 5, line 30-47). Therefore the anion/cation balance, urine pH must have been as in the instant invention, in the cows that need regulation. Itago is cited as describing the form of lysine, arginine and or nithine salts (p.3, col. 4, lines 41-46, and examples 2), one can use to make the products for ruminant. Davidson show adjusting cation/anion balance avoids milks fever, and urinary pH can be measured, and maintained at 6.5-5.5 (p.634).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize amino acid feed composition, to use one of Rode or Satin order to enhance milk production in high producing cows, with out metabolic imbalance shown by Davidson as providing Ca status so as to avoid milk fever. Itagaki discloses the form of the amino acids, any of which as shown by Rode, can be fed.

Applicant's arguments filed on 10/30/03 have been fully considered but they are not persuasive. Applicant's arguments have been carefully considered, but found wanting only limited compounds and circumstances dictate effective treatment, but applicant claims beyond support. The prior art shows one of ordinary skill to be able to monitor urinary pH for the condition of concern, and Rode shows treatment, Albert without applicants' monitoring, but to the same problem addressed. Feeding Rode

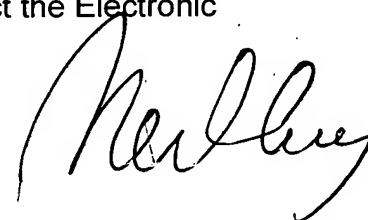
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would lead to pH change, but PTO cannot provide the laboratory to so show. Had applicant has such data to show Rodes lysine HCL fed 3 weeks pre-parturition did not result in pH as instantly claimed, then there would have been a case for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Levy/LR
February 5, 2004

NEIL S. LEVY
PRIMARY EXAMINER